

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of claims:

Claim 1 (previously presented): A self-emulsifying drug delivery system, wherein:
the system comprises a mixture of an extremely water-insoluble, lipophilic active agent; polyvinylpyrrolidone; a fatty acid; and a surfactant; and
the polyvinylpyrrolidone has a molecular weight of from about 2,500 to about 20,000.

Claim 2 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein:
the weight ratio of the fatty acid to the polyvinylpyrrolidone is from about 2:1 to about 1:3, and
the weight ratio of the surfactant to the polyvinylpyrrolidone is from about 10:1 to about 1:1.

Claim 3 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein:
the extremely water-insoluble, lipophilic active agent has a log P equal to or greater than 2, and
the extremely water-insoluble, lipophilic active agent has a solubility of less than 100 micrograms per milliliter of water.

Claims 4-5 (cancelled).

Claim 6 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the amount of polyvinylpyrrolidone is from 5% to about 40%, by weight of the self-emulsifying drug delivery system.

Claim 7 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the amount of fatty acid is from about 5% to about 35%, by weight of the self-emulsifying drug delivery system.

Claim 8 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the amount of fatty acid is from about 5% to about 15%, by weight of the self-emulsifying drug delivery system.

Claim 9 (original): The self-emulsifying drug delivery system of claim 1, wherein the fatty acid is a fatty acid containing from about 6 to about 18 carbons.

Claim 10 (original): The self-emulsifying drug delivery system of claim 9, wherein the fatty acid is selected from the group consisting of hexanoic acid, octanoic acid, nonanoic acid, decanoic acid, lauric acid, linoleic acid, oleic acid, palmitic acid, and mixtures thereof.

Claim 11 (original): The self-emulsifying drug delivery system of claim 1, wherein the surfactant is selected from the group consisting of polyoxylated castor oil, polyoxylated glycerides of fatty acids, polyoxyethylene sorbitan fatty acid esters, polyglycolized glycerides, and mixtures thereof.

Claim 12 (original): The self-emulsifying drug delivery system of claim 1, wherein the surfactant is selected from the group consisting of polyoxyl 35 castor oil and polysorbate 80.

Claim 13 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the amount of surfactant is from about 20% to about 70%, by weight of the self-emulsifying system.

Claim 14 (previously presented): The self-emulsifying drug delivery system of claim 13, wherein the amount of the surfactant is from about 30% to 50%, by weight of the self-emulsifying system.

Claim 15 (original): The self-emulsifying drug delivery system of claim 1, further comprising an antioxidant selected from the group consisting of ascorbic acid, ascorbyl palmitate, butylhydroxyanisole, butylhydroxytoluene, propyl gallate, sodium ascorbate, tocopherol, and mixtures thereof.

Claim 16 (original): The self-emulsifying drug delivery system of claim 1, further comprising a pharmaceutically acceptable organic solvent.

Claim 17 (original): The self-emulsifying drug delivery system of claim 14, wherein the solvent is selected from the group consisting of ethanol, a polyethylene glycol, propylene glycol, and mixtures thereof.

Claim 18 (previously presented): The self-emulsifying drug delivery system of claim 1, comprising:

from about 1 wt. % to about 4 wt. % the extremely water-insoluble, lipophilic active agent;

from 5 wt. % to about 40 wt. % the polyvinylpyrrolidone;

from about 5 wt.% to about 35 wt.% the fatty acid; and

from about 20 wt. % to about 70 wt.% the surfactant.

Claim 19 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the extremely water-insoluble, lipophilic active agent is a steroid, an anticancer agent, an antifungal agent, or antiinfective agent.

Claim 20 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the extremely water-insoluble, lipophilic active agent is selected from the group consisting of progesterone, ketoconazole, itraconazole, metroxyprogesterone, and paclitaxel.

Claims 21-24 (cancelled).

Claim 25 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the self-emulsifying drug delivery system is filled into a gelatin capsule.

Claim 26 (previously presented): The self-emulsifying drug delivery system of claim 25, wherein the gelatin capsule is a hard-shelled gelatin capsule, a soft-shelled gelatin capsule, or a hydroxypropyl methylcellulose capsule.

Claim 27 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the self-emulsifying drug delivery system is for oral administration.

Claim 28 (withdrawn – previously presented): A method of treating and/or preventing a condition in need of a therapeutic regimen comprising a steroid, an antifungal agent, an antibacterial agent, or an anticancer agent, wherein the method comprises administering a self-emulsifying drug delivery system of claim 1.

Claim 29 (withdrawn – previously presented): The method of claim 28, wherein the weight ratio of the surfactant to the polyvinylpyrrolidone is about 10:1 to about 1:1.

Claim 30 (withdrawn – previously presented): The method of claim 28, wherein:
the extremely water-insoluble, lipophilic active agent has a log P of equal to or greater than 2, and
the extremely water-insoluble, lipophilic anticancer active agent has a solubility of less than 100 micrograms per milliliter of water.

Claim 31 (withdrawn – previously presented): The method of claim 28, wherein the extremely water-insoluble, lipophilic active agent is selected from the group consisting of paclitaxel and an indolinone compound.

Claim 32 (withdrawn – previously presented): The method of claim 28, wherein the self-emulsifying drug delivery system is administered in combination with at least one additional active agent.

Claim 33 (withdrawn – currently amended): The method of claim 32, wherein the self-emulsifying drug delivery system is administered in combination with an active agent selected from the group consisting of vascular endothelial growth factor, 5-fluorouracil, leucovorin, irinotecanHC1, epirubicin, taxotere, taxol, carboplatin, gemcitabine, cisplatin, oxaliplatin, 5-azacitidine, **[[a]]** signal transduction inhibitor ~~inhibitors~~, a cytostatic compound, and mixtures thereof.

Claim 34 (withdrawn – previously presented): The method of claim 28, wherein the extremely water-insoluble, lipophilic active agent is selected from the group consisting of progesterone, ketoconazole, itrazone, and metroxyprogesterone.

Claim 35 (withdrawn – previously presented): Use of a self-emulsifying drug delivery system of claim 1 for the manufacture of a medicament, wherein the extremely water-insoluble, lipophilic active agent is selected from the group consisting of a steroid, an antifungal agent, an antibacterial agent, and an anticancer agent.

Claim 36 (withdrawn – currently amended): The use of claim 35, wherein the weight ratio of the fatty acid to the polyvinylpyrrolidone is from about 2:1 to about 1:3.

Claim 37 (previously presented): The self-emulsifying drug delivery system of claim 1, wherein the self-emulsifying drug delivery system is for parenteral administration.

Claim 38 (withdrawn – previously presented): The method of claim 28, wherein the weight ratio of the fatty acid to the polyvinylpyrrolidone is from about 2:1 to about 1:3.

Claim 39 (withdrawn – previously presented): The method of claim 28, wherein the self-emulsifying drug delivery system is administered orally.

Claim 40 (withdrawn – previously presented): The method of claim 28, wherein the self-emulsifying drug delivery system is administered parenterally.